Claim Rejection Under 35 U.S.C. § 103

Claims 50 to 127 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Durrani, *et al.*

In addition to remarks previously presented, Applicants note that Durrani, *et al.* is directed to forming powders that, upon rehydration, yield liposome-encapsulated drugs. To produce such powders, Durrani, *et al.* select unsaturated phospholipids, such as egg phosphatidylcholine, partially hydrogenated egg phosphatidylcholine and egg phosphatidylglycerol, as seen in all working examples of the cited document. The preference for egg phosphatidylcholine and egg phosphatidylglycerol also is noted at page 9, lines 3-5 of Durrani, *et al.* As discussed at page 9, lines 8-14 and 24- 26, the reference recommends using an additional lipid such as cholesterol. And in compositions that include single lipids, the lipid suggested Durrani, *et al.* is, again, egg phosphatidylcholine.

In contrast, Applicants' claimed phospholipids have saturated acyl groups. Furthermore, Applicants' claimed invention does not embrace additional lipids such as cholesterol, a typical component in liposome formulations.

To produce powders that, upon rehydration, yield liposome-encapsulated drugs, the cited document also recommends feed solutions having concentrations ranging from 3-4% w/v solids in the final solution, as seen at page 11, lines 31 to 35, in the working examples of Durrani, *et al.* and as required in Claim 1 of the cited document. These concentrations are considerably higher than the solute concentration of less than 1 weight/volume percent, claimed by Applicants in present Claims 50-69 and 91-108.

The presence of buffer salts is optionally embraced by amended Claims 50-69 and 91-108, and is explicitly required in new Claims 128-131. Applicants respectfully submit that Durrani, *et al.*, provides no motivation and teaches away from Applicants' invention, since, as discussed throughout the text and explicitly required in Claim 1 of the cited document, the spray dried powders taught by Durrani, *et al.* are formed in the absence of phosphate buffer salts.

Therefore, Claims 50 to 69 and 91 to 108, as amended herein, and new Claims 128-131 are patentable over Durrani, *et al.*

Information Disclosure Statement

An Information Disclosure Statement (IDS) is being filed concurrently herewith. Entry of the IDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned at (781) 861-6240.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Anabela C. Taylor

Anabela Cristina Taylor
Registration No. 38,999
Telephone (978) 341-0036
Facsimile (978) 341-0136

Concord, Massachusetts 01742-9133
Dated: October 18, 2001

MARKED UP VERSION OF AMENDMENTS

Claim Amendments Under 37 C.F.R. § 1.121(c)(1)(ii)

50. (Amended) A method for producing spray-dried particles having improved stability of a protein comprising:

(a) combining a protein, a phospholipid having saturated acyl chains, [and] a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, and, optionally, a buffer salt, to form a mixture having a solute concentration of less than 1 weight/volume percent; and

(b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;

wherein the particles consist essentially of the protein, [and] the phospholipid and, optionally, the buffer salt, and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

59. (Amended) The method of Claim 50 wherein the solute [protein and phospholipid] concentration in said mixture is at least 0.1 weight/volume %.

69. (Amended) A method for producing spray-dried particles having improved stability of a peptide comprising:

(a) combining a peptide, a phospholipid having saturated acyl chains, [and] a co-solvent, said co-solvent including an aqueous solvent and an organic solvent, and, optionally, a buffer salt, to form a mixture having a solute concentration of less than 1 weight/volume percent; and

(b) spray-drying said mixture to produce spray-dried particles having improved stability of the peptide;

wherein the particles consist essentially of the peptide, [and] the phospholipid and, optionally, the buffer salt, and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

91. (Amended) A method for producing spray-dried particles having improved stability of a protein comprising:

(a) combining a protein, a phospholipid having saturated acyl chains, [and] an organic solvent, and, optionally, a buffer salt, to form a mixture having a solute concentration of less than 1 weight/volume percent; and

(b) spray-drying said mixture to produce spray-dried particles having improved stability of the protein;

wherein the particles consist essentially of the protein, [and] the phospholipid and, optionally, the buffer salt, and wherein the phospholipid is present in the particles in an amount of at least about 10 weight percent.

100. (Amended) The method of Claim 91 wherein the solute [protein and phospholipid] concentration in said mixture is at least 0.1 weight/volume %.